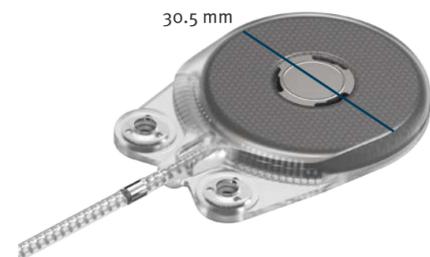


Product Overview

General technical specifications on Neuro Zti cochlear implant



4.5 mm
3.9 mm W/O silicone



Mechanical Properties	
Weight	10.5 g
Receiver thickness	Ranging from 4.0 mm (centre) to 4.5 mm (edge)
Receiver encapsulation	Titanium (base) – Zirconia (top) – Silicone envelope
Fixation system	Two shape-conforming silicone wings with titanium inserts
Impact resistance	2.5 joules (following the EN 45502-2-3:2010 standard)
Reference electrode	1 cylindrical ground electrode

Stimulation Features	
Stimulation Mode	Combined stimulation: monopolar mode and common ground stimulation.
Default Grounding	Intra and extra cochlear cathodic grounding
Pulse shape	Balanced biphasic pulses
Stimulation Frequency	Max.: 47500pps (20 electrodes) Software limited: F: 1040 Hz per channel

Diagnostic – Objective Measurements	
Impedance Measurements. Measurement of the implant's power. Electrically evoked Compound Action Potential Neuro ECAP. Psychoacoustic tests (Integrity EABR, ESRT). Implant recognition	

Safety	
Surgery	Minimal incision Two self-tapping screw fixation system Reduced cochleostomy (diameter: 0.8mm/1 mm) RW compatible
MRI safety level	MRI conditional at 3T with magnet removed MRI conditional at 1.5T with magnet in place

Cochlear Implant System Product Information Neuro Zti cochlear implant range

The ultra-compact Neuro Zti implant results from more than 25 years experience in cochlear implant development, manufacturing know-how and material science expertise. The Neuro Zti provides a powerful and future-ready electronic architecture. Its proven electrode arrays are designed to provide the best solution to fit the patient's cochlear anatomy, medical history and surgical needs.

Zr Ti The ultra-compact design

“Zti” is short for Zirconia and Titanium: two innovative, biocompatible materials widely used in the medical field. They make the Neuro Zti design highly resistant to impact, meeting the 2.5 J industry standard. The toughened Zirconia cover of the Neuro Zti receiver can resist up to 7 joules. The Zirconia material is transparent to radio waves allowing direct communication with the sound processor. The delicate implant antenna can therefore be protected and integrated in the core of the receiver. As a result, the Neuro Zti is able to deliver the smallest surgical footprint in the industry. The Neuro Zti ultra-compact design also means greater cosmetic freedom with respect to its placement on the head - closer to the ear, which may result in a more ergonomic fit for the sound processor.

Low-trauma fixation system

The Neuro Zti implant features a 2nd generation low-trauma fixation system to secure the implant in place. The shape-conforming flexible wings with titanium inserts allow the Neuro Zti implant to easily adapt to any skull surface. The Neuro Zti design eliminates the need for bone-bed drilling and suturing to secure the implant. The Neuro Zti fixation system minimizes the risk of device migration while significantly reducing surgical time (1) when compared to traditional fixation methods.

A powerful, future-ready technology

With the foundation of a powerful platform, the Neuro Zti implant offers precision sound delivery with 24 independent current sources. The entire signal processing architecture has been designed for stimulation precision in coordination with the external processing with the aim of maximizing the hearing experience. The Neuro Zti delivers an innovative bridge to support the most advanced sound processing strategies now and in the future.

MRI peace of mind

The Neuro Zti features a removable magnet. Removing or replacing the magnet is made very easy by the use of the Neuro Zti magnet extractor. The Neuro Zti is Magnetic Resonance Imaging (MRI) exam safe at 3 Tesla with the magnet removed and at 1.5T with the magnet in place. (*Before any MRI exams, a form must be filled in and returned to Oticon Medical Customer Service. www.oticonmedical.com)

Proven atraumatic electrode arrays

The Neuro Zti offers two different shape-conforming straight electrode arrays choices. They are both designed for low-trauma insertion with an optimal combination of mechanical and electrical properties.



Product features:

- Ultra-compact structure
- Smallest surgical footprint
- No bone-well needed
- 2nd generation low-trauma fixation system
- MRI exam safe at 1.5T
- MRI exam safe at 3T with magnet removed
- Proven atraumatic electrode arrays
- Full cochlear coverage
- Full-band electrode
- 24 independent current sources
- Safe implant recognition
- Dedicated ECAP chip on board

Product Range:

- Neuro Zti^{CLA}
- Neuro Zti^{EVO}

Product Indications:

- Adults and children who have severe-to-profound unilateral or bilateral sensorineural hearing loss, with limited benefit from appropriately fitted hearing aids.

Because sound matters

Oticon Medical is a global company in implantable hearing solutions, dedicated to bringing the magical world of sound to people at every stage of life. As a member of one of the world's largest groups of hearing health care companies, we share a close link with Oticon and direct access to the latest advancements in hearing research and technologies. Our competencies span more than a century of innovations in sound processing and decades of pioneering experience in hearing implant technology.

By working collaboratively with patients, physicians and hearing care professionals, we ensure that every solution we create is designed with user needs in mind. We share an unwavering commitment to provide innovative solutions and support that enhance quality of life for people wherever life may take them. Because we know how much sound matters.



Oticon Medical
Neurelec S.A.S
2720 Chemin Saint-Bernard
06220 Vallauris - France
Tel. +33 (0) 4 93 95 18 18 – Fax + 33 (0) 4 93 95 38 01
Email: info@oticonmedical.com

Electrode arrays versions Neuro Zti^{CLA} and Neuro Zti^{EVO}

Neuro Zti^{CLA}



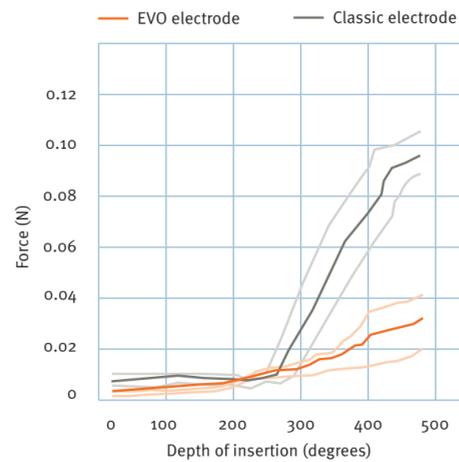
The CLASSIC electrode array has an optimized stiffness profile that makes it compatible with typical and difficult insertions. It is straight with a shape conforming structure and has dimensions that facilitate deep cochlear insertion (26mm). The soft-end of the electrode array is designed to reduce cochlear trauma. The push-rings at the base provide a “safe” point to manipulate and hold the array. They enable improved array insertion as well as mechanical sealing of the cochlea designed to minimize the risk of infection and/or CSF (cerebrospinal fluid) leakage.

Neuro Zti^{EVO}

The atraumatic electrode array



The EVO electrode array is designed to preserve the fragile structures of the cochlea, particularly important when there is residual hearing. Its smooth surface, small diameter, thin end and flexibility are designed to ensure a smooth, trauma-free insertion so that the cochlear structures are preserved as much as possible. Similar to the CLASSIC array, the EVO has push-rings at the base to make it easier to seal the array's entry point into the cochlea to help minimize the risk of infection and/or CSF leakage.



Proven atraumatic

The efficacy of our electrode arrays have already been proven. The specific characteristics of the EVO significantly reduce insertion forces by 32% (2) compared to the CLASSIC electrode array.

Product Overview

	Neuro Zti ^{CLA} M80184	Neuro Zti ^{EVO} M80185
Material components	Platinum iridium, silicone	
Number of independent active electrodes	20 full-band electrodes	
Insertion length	26 mm	25 mm
Active length	25 mm	24 mm
Cochleostomy size	Diameter: 1 mm	Diameter: 0.8 mm
Dimensions	Active area: 0.39 mm ² to 0.77 mm ² Diameter at apex: 0.5 mm Diameter at base: 1.07 mm	Active area: 0.46 mm ² to 0.60 mm ² Diameter at apex: 0.4 mm Diameter at base: 0.5 mm
Electrode array shape	Straight with shape-conforming Shape at the base: Extra-cochlear push-rings (2*1.5 mm)	Straight with shape-conforming Smooth Shape at the base: Extra-cochlear push-rings (1*1.5 mm, 1*1.2 mm)

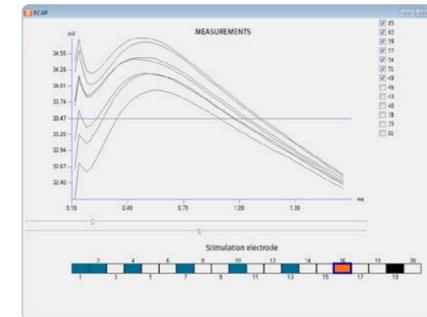
Oticon Medical's electrode

The Neuro Zti full-band electrodes are manufactured using a precise and highly-reproducible micro-machining process. This full-band shape is designed to allow an optimized orientation in the cochlea, to offer a reduced impedance and a low-charge density stimulation.



Neuro ECAP 1.0

The Neuro Zti electronic platform contains a dedicated DSP for measuring and analysing neural responses. Neuro ECAP 1.0 leverages the power of the ECAP DSP to allow the clinician to efficiently measure electrophysiological responses from the cochlea. Such measures may be useful for device function verification, understanding patient outcome and for creating mapping for patients where limited behavioral data are available. Basic and advanced electrophysiology capability are available.



Product Overview

Surgical tools and accessories

Non-sterile surgical tools			
			
M80173 Neuro Zti screwdriver	M80175 Insertion Forceps (Neuro Zti ^{EVO})	M80306 Insertion Fork (Neuro Zti ^{CLA})	M80176 Processor indicator

Sterile accessories		
		
M80181 Probe-array	M80174 Neuro Zti fixation screws	M80180 Neuro Zti implant indicator

Magnetic Resonance Imaging (MRI) exam with magnet removal.

Sterile components		Non-Sterile surgical tool
		
M80178 Neuro Zti magnet	M80179 Neuro Zti dummy magnet	M80177 Neuro Zti magnet extractor

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- (2) Nguyen Y., Miroir M., Kazmitche G., Sutter J., Bensidhoum M., Ferrary E., Sterkers O., Bozorg Grayeli A. Cochlear Implant Insertion Forces in Microdissected Human Cochlea to Evaluate a Prototype Array. Audiol Neurotol. 2012; 17: 290-8.